CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 606 **VERSION: As introduced February 22, 2007**

AUTHOR: Scott **SPONSOR: California Public Interest Research Group**

RECOMMENDED POSITION:

SUBJECT: Pharmaceutical information: clinical trial data

EXISTING LAW:

Regulates the packaging, labeling and advertising of food, drugs and cosmetics.

THIS BILL WOULD:

1. Create the Pharmaceutical Drug Information and Safety Act
2. Define a clinical trial as a clinical investigation as defined by the federal FDA
3. Define pharmaceutical company as any entity that is engaged in the production, preparation, propagation, compounding, conversion or processing of pharmaceutical drugs, either directly or indirectly, by means of chemical synthesis or by a combination of extraction and chemical synthesis. A pharmaceutical company as defined also includes an entity engaged in the packaging, repackaging, labeling, relabeling or distribution of pharmaceutical drugs or persons engaged in pharmaceutical detailing, promotional activities or other marketing of a pharmaceutical drug
4. Define pharmaceutical drug as any drug which is approved by the federal FDA and commercially available in this state
5. Define a Phase I Trail as the initial studies designed exclusively to determine the metabolic and pharmacologic actions of drugs in humans, and the side effects associated with increasing doses, and to gain early evidence of effectiveness
6. Requires any pharmaceutical company to make publicly available the results of every completed clinical trial, except for a phase I trail, that the company conduct for every drug that the company sells, delivers, offers for sales, or gives away in this state
7. Detail the information required to include:
    a. The name of the trial
    b. Commercial and chemical name of all pharmaceutical drugs tested, including comparator drugs
    c. Dosages tested for each drug, including comparator drugs

d. Initiation and completion dates of the trial
e. Purposes of the trial, include the medical condition or conditions studied
f. Outcomes of the trial including all time points at which outcome data were measured
g. Trial funding sources
h. Number of patients initially enrolled in the trial
i. Number of patients completing the trial
j. A list of all specific characteristics used to include and exclude people as trial participants, such as gender, race, age, preexisting health conditions, and an explanation of why each characteristic was used to include or exclude patients
k. Names and contact information for principal sponsors of the trial to include at least the phone number, mailing address and e-mail address for public inquiries
l. Names and contact information for principal researchers of the trial
m. Frequency, severity and nature of all adverse events experienced by trial participants, including participants that did not complete the trial for each drug
n. All information regarding the relative efficacy of each drug and the relative frequency, severity and nature of all adverse events experienced by trial participants if the study involved a comparison of two or more pharmaceutical drugs
o. A complete citation and, if available a hyperlink for any publications of the data from the study
p. The name and employer of each author of the study, including the ghostwriters
q. Any financial interest the principal researches of the study have in the drugs tested or compared in the trial and in the principal sponsors of the trial
r. A copy of the package insert for the drug that includes any adverse events to the drug

8. Require any pharmaceutical company to make publicly available an explanation of noncompletion for any clinical trial that the pharmaceutical company initiates or sponsors initiate, but does not complete for every pharmaceutical drug that the company sells, delivers, offers for sale or gives away. The explanation shall include the reason why the trial was terminated
9. Require that the trial information shall be submitted for inclusion on the Web site administered by the National Institutes of Health or on another publicly accessible Web site directly linked to the pharmaceutical company's primary corporate Web site. A publicly accessible Web site must provide free, nonsubscription access to its contents and clearly indicate the location and instructions for downloading the files or information submitted
10. Establish timelines for compliance with this section

AUTHOR'S INTENT:

According to the author's office, this bill is to address the concern that consumers do not have enough access to information regarding pharmaceutical drugs and their testing history.

FISCAL IMPACT:

The board is awaiting clarification from the author's office on certain provisions. Until then it is difficult to anticipate any potential fiscal impact on the board.

COMMENTS:

The intent of this legislation appears to be full disclosure to consumers about the prescription medications they are taking. However, the language in the bill and the requirements included expand to not only the drug manufacturers, but also the wholesalers, pharmacies, physician's offices, etc. that dispense these medications.

HISTORY:

2007
Mar. 8 To Com. on HEALTH.
Feb. 23 From print. May be acted upon on or after March 25.
Feb. 22 Introduced. Read first time. To Com. on RLS. for assignment. To print.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 1436 **VERSION: As Amended April 9, 2007**

AUTHOR: Hernandez **SPONSOR: CA Association for Nurse Practitioners**

RECOMMENDED POSITION:

SUBJECT: Nurse practitioners: scope of practice.

EXISTING LAW:

1. Defines the scope of practice for nurse practitioners.
2. Allows a nurse practitioner to dispense drugs pursuant to a protocol and specifies the conditions under which this can be done.
3. Details the requirements for a certificate evidencing that a person is qualified as a nurse practitioner.
4. Specifies the information required on a written order for a prescriber.

THIS BILL WOULD:

1. Expand the scope of practice for nurse practitioners and nurse midwives to include direct and indirect patient care services that include the administration of medications and therapeutic agents necessary to implement a treatment, disease prevention or rehabilitation regimen order in clinics, home health agencies, physician's offices and public or community health services.
2. Allow a registered nurse to dispense drugs or devices upon the order of a nurse practitioner or nurse midwife within a licensed clinic.
3. Allow a nurse practitioner to independently dispense drugs.
4. Alter the requirements for recognition as a nurse practitioner to include requiring a master's degree or doctoral degree in nursing as well as certification by a nationally recognized body approved by the Board of Registered Nursing.
5. Expand the scope of practice for a nurse practitioner to also include:
   - Perform a comprehensive history and physical examination
   - Establish diagnoses for physical, mental or emotional ailments or potential ailments
   - Admit patients to hospitals and nursing facilities
   - Order, perform and interpret laboratory, radiographic and other diagnostic tests
   - Identify, develop, implement and evaluate a plan of care for a patient to promote, maintain and restore health

- Perform therapeutic procedures to ensure that the nurse practitioner is qualified by education and experience to perform
- Prescribe treatments
- Prescribe and dispense medications when granted authority by the Board of Registered Nursing
- Refer patients to appropriate licensed physicians and surgeons or other health care providers
- Provide emergency care
- Perform additional acts that the nurse practitioner is educationally prepared for and clinically competent to perform
- Sign death certificates, return-to-work, school certificates and other related health certification forms
- Sign handicapped parking applications
- Order home health services
- Order durable medical equipment

6. Independently Prescribe Schedule II through Schedule V controlled substances
7. Prohibit a nurse practitioner from prescribing drugs or devices unless the Board of Registered Nursing has certified that a nurse practitioner has completed at least six months of supervised experience in the prescribing of drugs and devices
8. Require a nurse practitioner to register with the US DEA
9. Remove the reference to the protocol requirement for naturopathic doctors
10. Update Business and Professions Code section 4024(a) to include nurse practitioner
11. Update Business and Professions Code section 4040 (a)(2) to include nurse practitioner
12. Update Business and Professions Code section 4060 to allow a nurse practitioner to possess a controlled substance
13. Update Business and Professions Code section 4061 to allow a nurse practitioner to obtain samples
14. Update Business and Professions Code section 4170 to include a licensed or certification as a nurse practitioner who is registered by the Board of Registered Nursing
15. Remove all references to a nurse practitioner performing duties pursuant to a protocol
16. Require that any regulations promulgated by a state department, board, commission or bureau that affect the scope of practice of a nurse practitioner shall be developed in consultation with the Board of Registered Nursing
17. Allow a nurse practitioner to independently prescribe drugs and devices, including controlled substances when the drugs or devices prescribed are consistent with the practitioner's educational preparation or for which clinical competency has been established and maintained
18. Allow a nurse practitioner to prescribe Schedule II drugs in collaboration with a physician and surgeon or osteopath

19. Prohibit a nurse practitioner from prescribing drugs and devices until the Board of Registered Nursing has certified the completion of six months of supervised experience in the prescribing of drugs and devices in advance
20. Amends Business and Professions Code section 4024 to include a nurse practitioner under the definition of "dispense"
21. Amends Business and Professions Code section 4040 to include a prescription issued by a nurse practitioner
22. Amends Business and Professions Code section 4060 to allow a nurse practitioner to possess controlled substances
23. Amends Business and Professions Code section 4061 to allow a nurse practitioner to obtain drug samples
24. Require that each written request for drug samples to include the change of the physician and surgeon, certified nurse-mid wife, nurse practitioner, physician assistant or naturopathic doctor
25. Allow a certified nurse midwife, physician's assistant or naturopathic doctor to provide a properly labeled prescription drug prepackaged by a nurse practitioner
26. Amends the definition of "prescriber" to include a licensed and certified nurse practitioner
27. No longer requires the Board of Pharmacy from notifying the Board of Registered Nursing for complaints received related to the dangerous drugs and devices dispensed by a nurse practitioner
28. Removes the ability of the Board of Registered Nursing from handling complaints involving serious bodily injury due to the dispensing of dangerous drugs and devices by nurse practitioners
29. Amends the definition of practitioner found in Health and Safety Code Section 11026
30. Allow a nurse practitioner to become a Medi-Cal provider

AUTHOR'S INTENT:

The board is awaiting a response from the author's office.

PRIOR HISTORY/RELATED BILLS:

Several of the provisions found in this bill mirror the expanded scope of practice for nurse practitioners also found in SB 809.

FISCAL IMPACT:

The board is awaiting clarification from the author's office on certain provisions. Until then we are unable to determine if there will be a fiscal impact on the board.

COMMENTS:

This bill was significantly amended on April 9, 2007, and has expanded from the initial scope of the introduced legislation.

It is unclear what benefit to consumers would result if the board would be prohibited from notifying the Board of Registered Nursing when a complaint is received regarding a violation of Business and Professions code and is of concern that the Board of Registered Nursing could not investigate a complaint on a nurse practitioner for allegations of serious bodily harm due caused by dispensing. As amended, this legislation would compromise. Board staff is seeking clarification on these changes.

While this bill primarily focuses on nurse practitioners, it also expands the scope of practice for nurse midwives in a clinic setting.

HISTORY:

2007
Apr. 10 Re-referred to Com. on B. & P.
Apr. 9 Referred to Coms. on B. & P. and HEALTH. From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
Feb. 26 Read first time.
Feb. 25 From printer. May be heard in committee March 27.
Feb. 23 Introduced. To print.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 966 **VERSION: As Amended April 9, 2007**

AUTHOR: Simitian and Kuehl **SPONSOR: Constituent**

RECOMMENDED POSITION:

SUBJECT: Pharmaceutical drug disposal

EXISTING LAW:

1. Existing law is silent on how a consumer should dispose of unused medication.

THIS BILL WOULD:

1. Make findings and declarations related to the presence of drugs in streams and the negative effects on fish and other aquatic species.
2. Discuss the potential impact this may have on human health.
3. Establish a program through which the public may return and ensure the safe and environmentally sound disposal of prescription drugs.
4. Define "consumer" as an individual purchaser or owner or a drug
5. Define "drug" as articles recognized in the official United States Pharmacopoeia, the official National Formulary, the office Homeopathic Pharmocopoeia of the United States, or any supplement of the formulary of those pharmacopoeia. "Drug" also includes any articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or other animals, or articles, excluding food, intended to affect the structure or any function of the body of humans or other animals
6. Define "retailer" as a person or entity who makes a retailer sale of a drug to a consumer in this state and excludes a veterinarian that disposes of drugs that he or she did not personally manufacture or sell
7. Define "sale" as transactions conducted through sales outlets, catalogs, or the Internet, or any other similar electronic means, but does not include a sale that is a wholesale transaction with a distributor or retailer.

8. Require on or after July 1, 2008, that every retailer shall have a system to accept drugs for proper disposal.
9. Require the system to:
    - Be at no cost to the consumer if it is the type or brand which the retailer sold previously
    - Provide a notice to consumers that provides consumers access to obtain more information about opportunities and locations for no-cost drug recycling
    - Provide information about the retailer's drug return opportunities and encouraging consumers to utilize those opportunities. The information may include signage that is prominently displayed and easily visable to the consumer, written materials provided to the consumer at the time of purchase, reference to drug take-back opportunity in retailer advertising or other promotional materials or direct communications with the consumer at the time of purchase

AUTHOR'S INTENT

This bill was introduced upon recommendation of a constituent. The language is modeled after a similar bill that defined a dry cell battery as a household waste and requires retailers to accept these back to ensure appropriate disposal.

FISCAL IMPACT:

The board does not anticipate any major fiscal impact to the board. Minimal fiscal impact could be absorbed within existing resources of the board.

COMMENTS:

We recognize the need for the intent of this legislation, but are concerned that the appropriate balance is not achievable given the language of the bill as introduced.

The author's office has been in contact with the board and appears willing to accept amendments that could potentially ease the burden on pharmacies, without compromising the intent of the legislation.

The board's Enforcement Committee recently heard concern from a representative of Omnicare who stated that the return of prescription drugs from patients in Long Term Care is problematic as no mechanism is

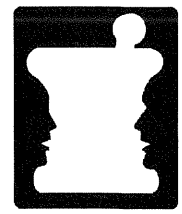
in place to allow for this to occur. Absent any regulation, there is no safeguard to ensure that the returned medications will not be diverted.

HISTORY:

2007
Apr. 9 Read second time. Amended. Re-referred to Com. on B., P. & ED.
Mar. 29 From committee: Do pass as amended, but first amend, and re-refer to Com. on B., P. & E.D. (Ayes 4. Noes 2. Page 385.) Set for hearing April 23.
Mar. 19 Set for hearing March 26.
Mar. 15 To Coms. on E.Q., B., P. & E.D. and RLS.
Feb. 26 Read first time.
Feb. 24 From print. May be acted upon on or after March 26.
Feb. 23 Introduced. To Com. on RLS. for assignment. To print.

Revised April 17, 2007

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS



BILL NUMBER: SB 472 VERSION: As amended April 16, 2007

AUTHOR: Richardson SPONSOR:

RECOMMENDED POSITION: None

SUBJECT: Pharmacies: prescription labels

EXISTING LAW:

1. Details the labeling requirements for a prescription container.
2. Prohibits a pharmacist from dispensing a prescription that does not meet the labeling requirements

THIS BILL WOULD:

1. Makes findings about the cost of health care and prescription drugs
2. Makes findings about the number of medication errors and sites some causes for these errors.
3. States that it is the intent of the Legislature to adopt a standardized prescription drug label that will be designed by a panel appointed to work with the California State Board of Pharmacy and that will be implemented in all pharmacies in California.
4. Require the board, in consultation with professionals in the field, to convene a prescription drug label panel to review and made recommendations regarding the standardization of prescription drug labels
5. State that a majority of the panel shall be from groups representing consumers, such as seniors and groups representing those with special issues regarding language and cultural competency in the use of prescription drugs.
6. Require the board to adopt a standardized label for prescription containers as recommended by the panel to include the following requirements
   - Is understandable for prescription drug users

- Describes the contents of the container so that consumers with a 4th grade reading level can understand
- Displays necessary information about properly taking the medication so that consumers with a 4th grade reading level can understand
- Displays mandated warnings in so that consumers with a 4th grade reading level can understand
- Implementation of the standardized label is affordable for pharmacies

7. Require pharmacy consultations by a telephone translation service to be available to patients with limited English language proficiency. Allow a pharmacy to issue translated labels for prescriptions, provided that the labels are found to be safe and reliable.
8. The panel must be established and begin meetings as soon as possible after January 1, 2008.
9. Require the board to adopt a standardized prescription label on or before October 31, 2008 and shall report the finding to the appropriate committees of the Legislature.
10. Require all in-state pharmacies to begin using the standardized label on or after January 1, 2009.

AUTHOR'S INTENT:

To create a standardized prescription label.

FISCAL IMPACT:

The board anticipates a significant fiscal impact on existing resources if required to facilitate and sponsor all panel meetings. Additionally, the board would require a limited term staff person to ensure the success of the panel.

COMMENTS:

This proposal appears to address recommendations made in the Medication Error Panel Report.

HISTORY:

2007
Apr. 16 From committee with author's amendments. Read second time. Amended. Re-referred to Com. on B., P. & E.D.

Apr. 9 From committee with author's amendments. Read second time. Amended. Re-referred to Com. on RLS. Re-referred to Com. on B., P. & E.D. Set for hearing April 23.
Feb. 28 To Com. on RLS.
Feb. 22 From print. May be acted upon on or after March 24.
Feb. 21 Introduced. Read first time. To Com. on RLS. for assignment. To print.

Revised April 17, 2007

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 963 VERSION: As Amended on April 16, 2007

AUTHOR: Ridley-Thomas SPONSOR: BP& ED Committee

RECOMMENDED POSITION: None

SUBJECT: Regulatory boards: termination

EXISTING LAW:

1. States that all existing and proposed consumer-related boards or categories of licensed professionals shall be subject to review every four years to evaluate whether each board has demonstrated a public need for continued existence.
2. Provides that in the event the board becomes inoperative and is repealed, the Department of Consumer Affairs shall succeed the board with all the duties, powers, purposes, responsibilities and jurisdiction not otherwise repealed.
3. Establishes the appointment of board members.
4. Establishes the authorization to appoint an executive officer.

THIS BILL WOULD:

1. Continue to require all boards to submit a Sunset Review report no later than 22 months before each board is slated to shall become inoperative; the report must detail among other items, the board's purpose, enforcement priorities, fund condition and legislative efforts to improve its legislative mandate.
2. Require that in the event the board becomes inoperative or is repealed, a successor board shall be created within the Department of Consumer Affairs that shall succeed to and is vested with all of the duties, powers, purposes, responsibilities and jurisdiction not otherwise repealed or made inoperative of the board that it is succeeding.
3. States that the successor board shall have the same number of members and composition as the board that it is succeeding and that the members shall be appointed by the same appointing

power, for the same term and with the same membership requirements.

4. Allows the successor board to also have the same authority to appoint an executive officer.

AUTHOR'S INTENT

According to the author's office, the intent of this legislation is to determine or redefine the sunset review process. It is anticipated that the bill language will be amended in mid-April, in advance of the policy committee meeting.

FISCAL IMPACT:

It is difficult to anticipate the fiscal impact of this legislation, as the scope of potential changes would depend on legislation resulting from the Sunset Review process. At minimum the board would anticipate fiscal impact to cover the costs for orientation and training for new board members and executive officer.

COMMENTS:

This legislation does not release the board from the Sunset Review process, whereby the board's report will be due to the Legislature no later than May 2008. This bill would essentially reconstitute the board.

HISTORY:

2007

Apr. 16 From committee with author's amendments. Read second time. Amended. Re-referred to Com. on B., P. & E.D.

Mar. 29 Set for hearing April 23.

Mar. 15 To Com. on B., P. & E.D.

Feb. 26 Read first time.

Feb. 25 From print. May be acted upon on or after March 27.

Feb. 23 Introduced. To Com. on RLS. for assignment. To print.